

**REMARKS**

Claims 1-45 are currently pending. Claims 1-2 and 4-12 have been amended, claim 3 has been cancelled, and claims 9-45 have been withdrawn as being directed to non-elected subject matter. Claim 1 has been amended to incorporate limitations from cancelled claim 3, and claims 2 and 4-12 have been amended to refer to claim 1, instead of claim 0. Applicants respectfully request reconsideration and allowance of all pending claims.

**1. Rejection of the claims under 35 U.S.C. §102**

Reconsideration is requested of the rejection of claims 1-2 and 4-7 under 35 U.S.C. §102 as being anticipated by Koike, et al. (U.S. 2004/0062847).

As amended, claim 1 is directed to a lipid system comprising naturally occurring oils comprising alpha-linolenic acid (C18:3n-3), omega-6 fatty acids, and omega-9 fatty acids, wherein the ratio of said omega-6 fatty acids to said alpha-linolenic acid (C18:3n-3) is from about 0.25:1 to about 3:1, and the ratio of said omega-9 fatty acids to said alpha-linolenic acid (C18:3n-3) is from about 1:1 to about 3:1.

Koike, et al. is directed to:

[A]n oil/fat composition comprising 5 to 99.9 wt.% of a monoglyceride having, as fatty acid constituents thereof, 15 to 90% of an  $\omega$  3-unsaturated fatty acid having less than 20 carbon atoms, 1 to 80% of an  $\omega$  9-unsaturated fatty acid, and 2 to 50% of an  $\omega$  6-

unsaturated fatty acid, and 0.1 to 49.9% of a diglyceride, wherein a weight ratio of the diglyceride to the monoglyceride is less than 1 and the content of a polyunsaturated fatty acid having at least 4 carbon-to-carbon double bonds is 20% or less of all the fatty acid constituents.<sup>1</sup>

Koike, et al. state that their oil/fat composition may contain a triglyceride and a free fatty acid.<sup>2</sup> Koike, et al. specifically disclose in Table 1, invention product #3, an oil/fat composition comprising 3.8% triglycerides, 32.0% diglycerides, and 64.2% monoglycerides, wherein the "MG-constituting fatty acids" include C18:3 n-3 (40.5%), C18:1 n-9 (34.3%), C18:2 n-6 (14.0%), C16:0 (7.7%), and C18:0 (3.0%). Koike, et al. emphasize, however, that the fatty acid profiles provided in Table 1 are the profiles of the monoglyceride component of the oil/fat composition, stating: "In Table 1, the oil/fat compositions thus prepared and analytical results of fatty acids constituting a monoglyceride are shown."<sup>3</sup>

Significantly, Koike, et al. fail to disclose a lipid system comprising naturally occurring oils comprising alpha-linolenic acid, omega-6 fatty acids, and omega-9 fatty acids, wherein the ratio of the omega-9 fatty acids to the alpha-linolenic acid (C18:3n-3) is from about 1:1 to about 3:1. At best, Koike, et al. disclose that the monoglyceride-constituting fatty acids in invention product #3 in Table 1 comprises 40.5% of C18:3 n-3 (i.e., alpha-linolenic acid), 34.3% of C18:1 n-9 (an omega-9 fatty acid), and 14.0% of C18:2 n-6 (an omega-6

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<sup>1</sup> Koike, et al. at paragraph 10.

<sup>2</sup> *Id.* at paragraph 17.

fatty acid). This equates to a ratio of omega-6 fatty acid to alpha-linolenic acid (C18:3 n-3) of 0.35:1, and a ratio of omega-9 fatty acids to alpha-linolenic acid (C18:3 n-3) of 0.85:1. This ratio, however, is outside of applicants claimed range of omega-9 fatty acids to alpha-linolenic acid set forth in amended claim 1 (i.e., from about 1:1 to about 3:1). Further, applicants note that neither invention product #1 nor #2, set forth in Table 1 of Koike, et al., have a ratio of omega-9 fatty acids to alpha-linolenic acid of from about 1:1 to about 3:1 in the monoglyceride component of the oil/fat composition.<sup>4</sup>

Additionally, applicants note that the fatty acid portfolios set forth in Table 1 of Koike, et al. correspond to the fatty acid portfolio of the monoglyceride component of the oil/fat composition.<sup>5</sup> However, as previously discussed, the oil/fat compositions set forth in Table 1 of Koike, et al. also comprise a triglyceride component, a diglyceride component, and/or a free fatty acid component. There is, however, no disclosure anywhere in Koike, et al. of how much omega-3 fatty acid, omega-6 fatty acid, or omega-9 fatty acid is present in

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<sup>3</sup> *Id.* at paragraph 52 (emphasis added).

<sup>4</sup> Invention product #1 has a ratio of omega-9 fatty acids to alpha linolenic acid in the monoglyceride component of the oil/fat composition of 0.22:1 (i.e., 12.8% of C18:1 n-9 and 58.9% of C18:3 n-3), and invention product #2 also has a ratio of omega-9 fatty acids to alpha linolenic acid in the monoglyceride component of the oil/fat composition of 0.22:1 (i.e., 13.1% of C18:1 n-9 and 58.8% of C18:3 n-3).

<sup>5</sup> See, e.g., Koike, et al. at paragraph 52 ("In Table 1, the oil/fat compositions thus prepared and analytical results of fatty acids constituting a monoglyceride are shown.") (emphasis added).

the triglyceride component, the diglyceride component, or the free fatty acid component of invention products 1, 2, or 3.

Nor would the oil/fat compositions set forth in Table 1 of Koike, et al. inherently have the same ratio of omega-6 fatty acids to alpha-linolenic acid and ratio of omega-9 fatty acid to alpha-linolenic acid, as set forth in applicants' amended claim 1, when all composition components (not just monoglyceride components) are considered. Applicants note that a finding of inherency cannot be based on *mere assumptions* by the Office. Rather, to establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."<sup>6</sup> Furthermore, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."<sup>7</sup>

In the instant case, the Office has pointed to nothing in Koike, et al. to suggest that the oil/fat compositions set forth in Table 1 of Koike, et al. have applicants' claimed ratios. As noted above, at best Koike, et al. set forth the ratio of omega-6 fatty acids to alpha-linolenic acid and ratio of omega-9 fatty acid to alpha-linolenic acid in the monoglyceride component of

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<sup>6</sup> MPEP §2112 (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

<sup>7</sup> MPEP §2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)). MPEP §2112 also states "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

invention products 1, 2, and 3 (with the ratio of omega-9 fatty acid to alpha-linolenic acid being outside of applicants' claimed range). There is, however, no disclosure or suggestion of what the fatty acid profile of the triglyceride, monoglyceride, or free fatty acid content of these compositions would be, or how the fatty acid profile of these components would affect the ratio of omega-6 fatty acids to alpha-linolenic acid and ratio of omega-9 fatty acid to alpha-linolenic acid in the overall composition.

As stated in MPEP §2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Since Koike, et al. fail to disclose a lipid system having a ratio of omega-6 fatty acids to alpha-linolenic acid of from about 0.25:1 to about 3:1 and, more particularly, a ratio of omega-9 fatty acid to alpha-linolenic acid of from about 1:1 to about 3:1, Koike, et al. fail to disclose each and every limitation of claim 1. As such, claim 1 is novel over the cited reference.

Claims 2 and 4-7 depend from claim 1 and are thus patentable over the cited reference for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

**2. Rejection of the claims under 35 U.S.C. §112, Second Paragraph**

Reconsideration is requested of the rejection of 2 and 4-8 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office has stated that claims 2-8 recite the limitation "as defined in claim 0," but that there is insufficient antecedent basis for claim 0.

As noted above, claims 2 and 4-8 have been amended to depend from claim 1, instead of claim 0. As such, applicants submit that the rejection of claims 2 and 4-8 under 35 U.S.C. §112, second paragraph has been overcome.

Applicants note that the only pending rejection of claim 8 is the above-recited rejection under §112, second paragraph. As claim 8 has been amended to address this rejection, applicants submit that claim 8 is now in condition for allowance.

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**CONCLUSION**

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-2 and 4-8 and allowance of all pending claims. The Commissioner is hereby authorized to charge any fees required in connection with this Amendment E to Deposit Account Number 01-2384 in the name of ARMSTRONG TEASDALE LLP.

Respectfully Submitted,

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